DEPARTMENT OF VETERANS AFFAIRS Justification and Approval For Other Than Full and Open Competition

1. Contracting Activity:

Department of Veterans Affairs, VISN 10, Louis Stokes Cleveland VA Medical Center through the Network Contract Office (NCO) 10. We are looking to procure using a Justification for Other Than Full and Open Competition.

2237 Transaction # or Vista Equipment Transaction #: 541-14-1-703-0620

2. Nature and/or Description of the Action Being Processed:

This action will be for the procurement of implants and disposable instruments to fill Podiatry surgical trays. A new firm-fixed price procurement will be for this action.

3. Description of Supplies/Services Required to Meet the Agency's Needs:

The Otorhinolaryngology Section requires the following Trilliant instrument/implants for use in the Operating Rooms at the Medical Center and Ambulatory Surgical Center. These items will supply the necessary instruments and implants to replenish surgical trays and reduce turnover time between cases.

scription/Part Number*			
Trilliant Surgical Grid	ock Plating	System	
IMATED DOLLAR VALUE: \$150	.225.00		

4. Statutory Authority Permitting Other than Full and Open Competition: .

(b) REQUIRED DELIVERY DATE: March 31, 2014

X	(1) Only One Responsible Source and No Other Supplies or Services Will Satisfy
	Agency Requirements per FAR 6.302-1;
)	(2) Unusual and Compelling Urgency per FAR 6.302-2;
)	(3) Industrial Mobilization, Engineering, Developmental or Research Capability
	or Expert Services per FAR 6.302-3;
)	(4) International Agreement per FAR 6.302-4
)	(5) Authorized or Required by Statute FAR 6.302-5;
)	(6) National Security per FAR 6.302-6;
)	(7) Public Interest per FAR 6.302-7;

5. <u>Demonstration that the Contractor's Unique Qualifications or Nature of the Acquisition Requires</u> the Use of the Authority Cited Above (applicability of authority):

The Cleveland VAMC, Podiatry Section is requesting the Implants/Instruments be manufactured by Trilliant. We currently own these sets and require more to support an increased case load at the medical center and in the new Ambulatory Surgery Center. For the types of cases being performed, all implant trays need to be uniform to prevent errors during surgery and while re-processing. All of the implants on the requested tray and the VA owned trays need to be 100% compatible with one another. Due to the proprietary nature of these implants and instruments, other manufacturer's items will not be compatible. Intermixing different manufacturer's implants/instrumentation can potentially lead to patient safety concerns.

6. <u>Description of Efforts Made to ensure that offers are solicited from as many potential sources as deemed practicable:</u>

Surgical Instrument/Implant manufacturers routinely create their products to be proprietary to their system only. This will unfortunately limit sources to those who distribute only specific brands. In the past the manufacturer, Trilliant, has distributed through two other sources to assist the government meet our small business goals.

- 1. Trilliant Surgical, LTD
- 2. American Medical Depot (Small Business)
- 3. Tidewater Management VOSB

Trilliant Surgical, LTD has stated they don't have any authorized distributors at this time.

7. <u>Determination by the Contracting Officer that the Anticipated Cost to the Government will be Fair</u> and Reasonable:

The pricing being offered by Trilliant is the same, or less, as would be offered to any other Federal or privately run hospital. Per FAR 6.303-2(7), Content, a determination by the contracting officer that the anticipated cost to the Government will be fair and reasonable.

8. <u>Description of the Market Research Conducted and the Results, or a Statement of the Reasons</u> Market Research Was Not Conducted:

Market research was conducted by reviewing the GSA, FSS and Open Market sources. Also, the Manufacturer was queried to determine if any other sources are available.

9. Any Other Facts Supporting the Use of Other than Full and Open Competition

An intent to sole source for RFQ VA250-14-R-0184 will be posted on FBO from February 26, 2014 through March 7, 2014.

10. Listing of Sources that Expressed, in Writing, an Interest in the Acquisition:

Trilliant Surgical, LTD 448 W 19TH STREET HOUSTON, TX 77008 800-495-2919

11. A Statement of the Actions, if any, the Agency May Take to Remove or Overcome any Barriers to Competition before Making subsequent acquisitions for the supplies or services required:

On-going research of the industry market place will be conducted to determine if there are new entrants into this product area.

12. Requirements Certification:

I certify that the requirement outlined in this justification is a Bona Fide Need of the Department of Veterans Affairs and that the supporting data under my cognizance, which are included in the justification, are accurate and complete to the best of my knowledge and belief.

VISN 10/Cleveland VAMC

13. Approvals in accordance with FAR 6.304

a. Contracting Officer's Certification (required): I certify that the foregoing justification is accurate and complete to the best of my knowledge and belief.

Thomas P. Moore Contracting Officer

2/24/14 Date

NCO 10

b. NCM/PCM (Required \$3K and above): I certify the justification meets requirements for other than full and open competition.

Terry Spitzmiller

Director of Contracting

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NCO 10

2/24/19 Date